Trulign™ Toric Accommodating Intraocular Lenses

PATIENT INFORMATION BROCHURE

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Glossary

Accommodation - The movement of the lens to focus on images at various distances.

Anesthesia For Cataract Surgery - The standard cataract surgery anesthetic are eye drops. The patient is awake during surgery, but may be given relaxing medication.

Aphakia - The absence of the eye's natural crystalline lens, after cataract removal.

Aphakic Spectacles - Thick, eyeglasses that were once the standard correction following removal of a cataract. The glasses were cumbersome and greatly distorted peripheral vision. Today, an intraocular lens (IOL) is implanted in the eye after the lens with a cataract is removed.

Astigmatism - Astigmatism is blurry vision produced by light in focusing at two different places in the eye, making both near and distance vision a problem.

Aspheric IOL - An artificial lens with an optic surface designed to enhance vision under low light conditions when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape.

Capsular Bag - The clear, thin, elastic membrane that holds the lens. When a cataract is removed, the replacement IOL is implanted into the capsular bag.

Cataract - An opacity or clouding and hardening of the crystalline lens that may prevent a clear image from forming on the retina and reduces the lens' ability to accommodate. The cataractous lens may require surgical removal and replacement with an intraocular lens if visual loss becomes significant.

Ciliary Muscle - Controls the focusing of the natural or artificial lens. When the muscle relaxes, the lens rests in the backwards position for distance vision. When it contracts, it increases the pressure in the vitreous which gently pushes the lens forward for near vision. As the lens enlarges and hardens, the ciliary muscle is unable to work as well.

Cornea - The transparent front segment of the eye that covers the iris and pupil, providing most of the eye's focusing power.

Crystalline Lens - The clear natural structure in the eye which is the primary focusing mechanism that helps to focus light on the back of the eye. The crystalline lens functions like the lens of a camera, made up of protein and water, located behind the iris, it changes shape and moves forward and back to focus images from various distances onto the retina.

Corneal Astigmatism - Different curvatures on the cornea which causes blurred vision by focusing the light at two different places in the eye.

Diopter - A measurement of the degree to which light focuses; which relates to the power or strength of the lens.

Haptics - The two plates and/or tiny loops located on opposite sides of an intraocular lens that hold the lens securely in place. Trulign Toric IOL has patented hinges built into the haptics to allow gentle movement forward and backward to focus.

Hyperopia - Also known as farsightedness, is a refractive error caused by the eye being too short. Light focuses behind the retina and therefore strikes the retina before it can come to a sharp focus.

Intermediate Vision - Range of visual focus between 14" - 36", e.g., seeing the dashboard, prices in the supermarket, computer screen.

Intraocular Lens (IOL) - An artificial lens that replaces the natural crystalline lens of the eye after cataract surgery. The Trulign Toric IOL is a flexible IOL made of a proprietary advanced generation solid silicone called BioSil™.

Iris - The colored membrane in front of the natural crystalline lens that gives color to the eye (e.g., brown eyes) and controls the amount of light entering the eye by varying the size of the black opening (pupil). The iris constricts for near vision.

Monofocal IOL - An artificial lens designed to restore only one distance of vision.

Myopia - Also known as nearsightedness, is a refractive error caused by the eye being too long. In these cases light focuses in front of the retina.

Near Vision - Range of visual focus up to 14", e.g., reading, sewing, etc.

Ophthalmologist - A physician and surgeon specializing in refractive, medical, and surgical treatment of eye diseases and disorders.

Optic Nerve - Carries the visual information captured on the retina to the visual cortex of the brain for recognition and interpretation.

Optometrist - A primary eye care provider who diagnoses and treats disorders of the visual system, and manages and treats eye diseases.

Phacoemulsification (fay-koh-ee-mul-sih-fih-KAY-shun) - A cataract surgical procedure which uses an ultrasonic vibration to break up and remove a cataract through a tiny incision.

Point Size - A relative measure of the size of a font in type. 20/40 vision is equivalent to reading 6-point type, the size of the stock quotes in the newspaper or print in the telephone book. Most computers are set to 12-point type.

Presbyopia - Occurs as the lens of the eye ages, enlarges and becomes less elastic and less able to accommodate. Usually becomes significant after age 45 and is often signaled by the need for reading glasses or bifocals.

Pupil - The variable-sized, black circular opening in the center of the iris that controls the amount of light that enters the eye.

Retina - The light-sensitive layer in the back part of the eye that receives images (light) from the sensitive rods and cones that capture the visual images and sends them along the optic nerve to the brain for interpretation. The thin lining at the back of the eye that converts images from the eye's optical system into electronic impulses sent along the optic nerve for transmission to the brain.

Toric IOL - An artificial lens with an optic surface designed to correct corneal astigmatism.

Vitreous Humor - A transparent jelly and fluid that fills the section of the eye between the retina and the lens. When the ciliary muscle contracts, it increases the pressure in the vitreous which then gently pushes the lens forward.

YAG Laser - The YAG laser is a surgical instrument that emits a short pulsed, high energy light beam that can be precisely focused to treat a clouding of the remaining capsular tissue that envelopes the IOL. The surgery is performed on an outpatient basis, is done without an anesthetic usually in the office, takes only a few minutes and is painless.

Zonules - Thin fibers that attach the lens to the ciliary muscle. Thin fibers that ensure the stability of the lens, attaching it to the ciliary muscle.

Introducing Trulign™ Toric Accommodating IOL

This brochure provides information about the Trulign Toric Accommodating Intraocular Lens (IOL). Unlike other mono- or multifocal IOLs, this IOL is designed for correction of aphakia and postoperative refractive astigmatism and is dynamic within the eye, *moving continuously backward and forward* to bring images from various distances into focus with reduced dependence on glasses after cataract surgery. Your eye doctor will advise you about the potential risks and benefits of cataract removal and IOL implantation.

Please read this entire brochure carefully and consult with your doctor concerning any questions you have about the Trulign Toric IOL or the surgery. You can also obtain additional information by calling the manufacturer, Bausch + Lomb, toll-free at 866-393-6642 (USA).

What is a cataract?

Cataracts are a natural part of the aging process. More than 20 million Americans have cataracts. A cataract is a progressive thickening, hardening and clouding of the eye's lens. Because cataracts develop very slowly, the decline in vision can be difficult to detect. The first sign that your lens is hardening may be an increasing need for reading glasses. This is due to a loss of accommodation, the ability of the eye's lens to focus on images that are near (14 inches or closer), intermediate (14 to 36 inches from the viewer) and distance.

You use your **distance vision** when taking a walk or window-shopping.

Intermediate vision encompasses most daily activities, such as working on your computer or checking the instruments on your dashboard when driving.

Near vision is utilized for images such as reading, sewing or putting on makeup.

Loss of accommodation, also known as presbyopia, affects nearly everyone after age 40. It actually begins gradually at about age 10 and continues to decline, becoming noticeable when we begin to experience difficulty focusing on close objects or fine print. When this occurs, most people purchase reading glasses for occasional use. As the condition progresses, many people find they own several pairs and experience increased frustration at their growing dependence on them for daily life. When one is mature enough to develop cataracts, it may affect your ability to enjoy the things you used to do. In addition, you may experience changes in how you see colors, have problems with glare from lamps or the sun, begin to encounter double vision or see a frequent need for a new, stronger spectacles prescription.

Eventually, your physician will recommend cataract surgery, the most common and one of the safest procedures performed in the U.S. Removal of the opacified lens and replacement with an artificial lens (an intraocular lens implant) is the primary treatment for cataracts.

What is corneal astigmatism?

Astigmatism is a focusing error in the eye that results in blurred distance and/or near vision. In a normal eye, the cornea has a round shape (like a basketball); therefore, the light rays entering the eye focus at a single point on the back of the eye (retina) to form a clear image. In an eye with corneal astigmatism, the cornea has an oblong shape (like an American football). As a result, the light rays do not focus at the same point on the retina and parts of an object may not appear clear.

High levels of corneal astigmatism may also be associated with visual distortions (e.g. objects appear tilted or misshapen or floors appear curved). During your eye examination, your eye doctor will be able to tell you if you have corneal astigmatism.

What types of IOLs are available for treatment of corneal astigmatism?

The vast majority of available IOLs are monofocal. It is a technology that has been used successfully for decades. Monofocal toric IOLs are one option for correcting corneal astigmatism and distance vision after cataract surgery to provide clear vision at one focal point, usually distance vision. In most cases, however, the patient still needs to wear glasses or contact lenses to see images within their near field of vision and sometimes for those in the intermediate field of vision, as well. There are other IOLs to choose from for distance vision, but some are not designed to correct astigmatism. Your eye doctor will discuss the IOL options available to you.

Without accommodation, other options fall short; patients cannot adjust their vision from distance to intermediate and near.

Accommodation is the ability of the natural crystalline lens to adjust, and with the natural contractions of the muscle in the eye, to focus on objects through a range of near, intermediate, and far distances.

As with the natural lens, an accommodating IOL moves and flexes, in response to ciliary muscle contractions in the eye. These contractions drive forward movements of the lens so the eye can maintain a clear image as it focuses on near, intermediate and far objects. Trulign Toric IOL is the first and only astigmatism correcting accommodating lens approved by the FDA.

The Trulign Toric accommodating intraocular lens

- Plate Haptics and loops hold the lens in place
- Hinges allow lens to move gently forward and back
- Optic focuses the image on the retina

The Trulign Toric Accommodating IOL is designed to mimic the natural accommodating process of the eye. The exact mechanism of the lens has not been fully elucidated but it is designed to move backward and forward inside the eye using a hinge, which is located next to the optic of

the lens. The effect on the hinge for movement of greater than a million cycles has not been established. This dynamic enables the eye to automatically focus the lens on images that are within distant, intermediate and near fields of vision and can eliminate or reduces your need for glasses or contact lenses after surgery. Remember, while there is every reason to believe you will receive excellent results from your Trulign Toric Accommodating IOL, everyone's focusing capabilities are different. Your optimal vision solution may allow you to do most things without glasses while others may be more comfortable with spectacles for a certain task.

Clinical study results

The Parent Lens clinical study for the United States Food and Drug Administration involved 497 eyes in 324 adult patients over 50 years of age. Results of the study demonstrated the parent lens power to restore patients' vision and reconnect them with the most important aspects of their lives.

- 100% of patients implanted with the parent lens in both eyes could pass a driver's test without their glasses
- 100% could see intermediate (24" to 30"), the distance for most of life's daily activities, e.g., dashboard, prices in the supermarket, and their computer screen, without their glasses
- 98.4% could see well enough to read print the size of the stock quotes in the newspaper or read the phone numbers in the white pages of a telephone book without their glasses
- More than 80% reported they were using their computer, shopping and applying make-up without needing their glasses
- Some patients did require glasses for some tasks after implantation of the parent lens
- Significantly more patients implanted with the parent lens (88.4%) could see better at all distances than patients implanted with a standard IOL (35.9%).

The Trulign Toric IOL clinical study for the United States Food and Drug Administration involved 229 eyes in 229 adult patients (227 eyes in 227 patients were implanted). Results of the study demonstrated that the Trulign Toric Accommodating IOL effectively corrects astigmatism.

- 85% of the cases involving astigmatism that the surgeon intended to correct were remedied.
- Only 46.5% of the patients receiving a non-toric lens achieved the intended reduction in astigmatism.
- 100% of patients implanted with Trulign Toric IOL could pass a drivers' test without glasses.
- Only 75% of patients who were implanted with a non-toric lens could pass a drivers' test.

Benefits of Parent:

The parent lens clinical study involved nearly 500 eyes in more than 300 patients. The results indicated that almost all of the patients implanted in both eyes with the parent lens had good distance vision after surgery (i.e., they could see 20/32 or better at distance), all patients had good intermediate vision, which means that they could see a computer screen or items at arm's length, and the majority (98.4%) could read the newspaper without glasses. Almost all of the study patients had vision good enough to allow them to pass their drivers test, see their computer, shop, apply their makeup, or read a newspaper without glasses or contact lenses. Of those patients who had only one eye implanted, about 1 in 10 had their near and/or far vision worse than 20/40 after the surgery. Two in a hundred had their intermediate vision become worse than 20/40 after the surgery. In contrast, of those patients implanted with a standard IOL, about 6 in 10 had their near and/or far vision worse than 20/40 after the surgery. Six in a hundred had their intermediate vision become worse than 20/40 after the surgery.

In the clinical study, more than 85% of patients were able to drive with mild to no difficulty at night. In addition, nearly 85% of patients did not wear spectacles to see at night.

Benefits of Trulign Toric Accommodating IOL:

Trulign Toric Accommodating IOL is expected to provide all the benefits of a Monofocal Toric plus the additional benefits of Trulign Toric IOL quality of vision. The Trulign Toric IOL clinical study involved 229 eyes in 229 patients. The results indicated that the majority of patients had their pre-existing corneal astigmatism optically corrected after surgery, and more patients had clearer uncorrected distance vision with the corrected corneal astigmatism.

Cataract surgery is one of the most common surgical procedures performed; however, as with all surgeries there are warnings, precautions, and risk that you should be aware of.

Warnings

1. Your eye doctor may not be able to implant the Trulign Toric Accommodating IOL into your eye if you have complications during surgery (e.g. tissue damage that may cause the lens to rotate after surgery). Depending on your specific surgical complications your doctor may or may not be able to implant a different IOL during the same surgical procedure.
2. Contact your eye doctor immediately if you have any of the following symptoms while using the antibiotic eye drops prescribed by your doctor: itching, redness, watering of your eye, sensitivity to light. These symptoms could indicate a potential serious eye infection.

Precautions

1. As with any surgical procedure, there is risk involved. Possible complications from cataract surgery include infection, damage to the lining of the cornea, separation of the retina from the layer of tissue at the back of the eye (retinal detachment), inflammation or swelling inside or outside the eye, damage to the iris (the colored part of your eye), and an increase in eye pressure. You may need additional surgery to reposition or replace the IOL, or to

treat other surgery complications. Toric IOLs require surgical repositioning more often than non-toric IOLs.

2. Tell your eye doctor if you have been diagnosed with any eye disease. The safety and effectiveness of the Trulign Toric Accommodating IOL has not been established in patients with preexisting eye conditions and complications during surgery, such as an increase in eye pressure (glaucoma) or complications of diabetes in the eye (diabetic retinopathy). The outcome of cataract surgery will depend on the health of your eye before surgery.
3. You will need to wear glasses if you have any of the following:
   a. *Nearsightedness or farsightedness after surgery:* These conditions may result from errors in measurements before surgery, wrong lens power, or changes in the cornea in response to the surgery;
   b. *Uncorrected astigmatism after surgery:* This condition may result from the same reasons as stated above. In addition, uncorrected astigmatism could also result from improper position of the IOL or if your corneal astigmatism is greater than the amount that can be corrected with the IOL.
4. A toric IOL corrects astigmatism only when it is placed in the correct position in the eye. There is a possibility that the toric IOL could be placed incorrectly or could move within the eye. If the toric lens is not positioned correctly following surgery, the change in your astigmatism correction by the IOL, along with any necessary correction with glasses, may cause visual distortions.
5. Avoid any activity that could harm your eye while you are recovering from surgery.

Potential Risks

There are risks associated with cataract surgery. The complications and side effects experienced during the clinical study were similar to those experienced with other intraocular lenses and with routine cataract surgery. Because it is surgery it is not completely risk-free. Complications may occur as a result of the removal of your cataract whether or not an intraocular lens is implanted. Complications of cataract surgery range from minor, usually temporary side effects, to sight-threatening complications. Fortunately, significant sight-threatening complications are extremely rare and include, but are not limited to infection, hemorrhage, and retinal detachment. People with existing medical conditions such as diabetes and chronic eye infections are at a higher risk of developing complications.

You may have reactions to medicines, and side effects include redness, scratchiness of the eye, and sensitivity to light. Possible complications from cataract surgery include infection, bleeding, inflammation, tissue damage, tissue swelling of the front or back of the eye, or an increase in eye pressure. If your lens is not in the correct position, your vision may also be affected and the normal flow of fluid within the eye may be blocked. Your vision may not improve or may get worse if these complications occur. You may require additional surgery to treat these side effects.

The risks of implantation with the Trulign Toric IOL are the same risks that exist for all intraocular lenses. However, because the Trulign Toric IOL works by moving forward and backward in the eye, there is a risk of the lens becoming stuck in the forward position, giving you only good near vision. In this case, you will need spectacles or contact lenses to see at distance. If the lens becomes stuck in the backward position, it will give you good distance vision, like a standard intraocular lens, but you will need spectacles to read or to see near objects.

If you have high corneal astigmatism, you may notice that some objects appear tilted or misshapen or floors appear curved. These visual distortions may be present before cataract surgery but may remain after surgery if your astigmatism is not fully corrected or if the IOL is not in the proper position in your eye. It may take some time to adapt to your new IOL(s) and any changes in your astigmatism. Please discuss with your eye doctor about your vision and any symptoms after surgery.

Your eye doctor may advise that you have a second surgery if the toric IOL is not properly positioned in your eye.

The overall risks associated with cataract surgery, compared to other types of surgeries, is relatively low. Toric IOLs require surgical repositioning more often than non-toric OLs. Discuss any questions about the possible risks and benefits of cataract surgery and the Trulign Toric Accommodating IOL with your eye doctor.

Are you a candidate for the Trulign Toric Accommodating IOL?

Your doctor will perform a thorough examination to determine if you have a cataract, and advise you of the most appropriate option for correcting your vision. Depending upon your expectations, lifestyle and the presence of any pre-existing visual conditions, your ophthalmologist will determine whether you can benefit from the implantation of a Trulign Toric Accommodating IOL.

Virtually everyone with good general health is a candidate for implant surgery. Individuals with chronic eye infections, uncontrolled diabetes, or other health problems may have to wait until these conditions are managed before they have surgery.

People who have had prior corneal refractive surgery (for example, LASIK) are acceptable candidates for implantation as long as their eye is in good health. If you have already had cataract surgery, you are not a candidate.

Only you and your doctor can determine if Trulign Toric IOL is right for you.

What to expect

Cataract surgery is a procedure to replace your cloudy natural crystalline lens with an intraocular lens implant. You should expect the following before, during, and after surgery.

Before Surgery

You will need a thorough eye examination. Be sure to tell your eye doctor about any problems about your vision or general health. Your eye will be measured after you and your eye doctor have decided that you will have your cataract removed. This will determine your amount of corneal astigmatism and the IOL power that will be right for you. You should plan to have someone else drive you home.

Once selected as a candidate for the Trulign Toric IOL, be certain that you are comfortable with all aspects of your cataract surgery. Ask questions and inform your surgeon of any medications you are currently taking. Prior to surgery, you can expect:

- Pre-op visit- physician evaluations of your eye and vision needs
  This is your chance to ask questions of your doctor and share any specific visual needs you might have. For example, if you have a hobby or pastime, such as oil painting, golfing, playing the piano or gardening.

- Precise pre-op measurements
  Prior to surgery, your doctor will perform three tests that will measure your vision and help to ensure the results achieved by your Trulign Toric IOL are consistent with your expectations.
    - *Refraction-measures what you see compared to a standard scale, i.e. 20/20*
    - *Biometry-measures the length of the eye and tells the doctor the power of the lens to be placed in the eye*
    - *Keratometry-measures the amount your cornea is curved, bending light toward your lens*

During Surgery

Cataract surgery techniques vary widely. However, the eye is always numbed to make the operation painless. A few things to know for your day of surgery:

- Surgery with the Trulign Toric IOL is an outpatient procedure
- *Surgery is usually performed as an outpatient procedure and typically takes less than 20 minutes. However, you will need a friend or family member to take you home.*
- Your surgeon will use eye drops to anesthetize your eye and dilate your pupil
- Your nurse will cleanse and drape your eye
- You will be awake during the short procedure
- You will experience no pain, but there will be a slight pressure

To perform surgery, your doctor will use a microscope to have a magnified view of your eye to properly position the toric IOL. Your natural lens sits in a bag-like structure called the capsule. The capsule is located just behind the colored part of your eye (iris). A small incision is made on the clear front part of your eye (cornea) to reach and remove the cataract. An IOL is then placed into the capsule to replace your natural lens. The IOL will act in the same way as your natural lens to restore your distance vision. The eye doctor will usually place a shield over your eye to protect it after surgery. After a short stay in the outpatient recovery area you will be ready to go home. Your eye doctor will let you know when your vision is good enough to drive again.

After Surgery

After surgery, your eye doctor should give you a wallet card that identifies the type of implant in your eye. Typically, your eye doctor will examine you the following day. Many patients may see better within 1 to 2 days, most are stable at 10 to 14 days, but some may take 4 to 6 weeks to fully recover from the surgery. Improvements in vision are different for each individual. Take all prescribed medicines and apply antibiotic eye drops as instructed by your eye doctor. Be sure to consult your eye doctor if you have any questions or concerns as a result of cataract surgery.

It is important that you closely follow your doctor's instructions after surgery. Do not rub your eye since this could impair its healing. During the first day post-op it will be important to limit your activity. After that you should be able to perform all of your normal activities, including showering and swimming. In addition, during the first two weeks it is important to remember:

- Use glasses to read while your new lens *settles* within your eye
- Your pupils will be dilated, so you will not be able to focus near and you may experience glare
- Your intermediate vision will be slightly diminished, but will improve
- Your distance vision will not significantly diminish and will improve
- You may experience halos around bright lights because of the eye drops your doctor has given you. These side effects will quickly dissipate

AFTER TWO WEEKS, READ WITHOUT YOUR GLASSES AT LEAST TWICE A DAY FOR 10 MINUTES A SESSION.

Read the smallest type you are comfortable with. A Vision Restoration Card may be provided as a tool in re-training your eye muscles.

Among the most important things post-operatively will be for you to work the ciliary muscle back into shape. This is the muscle in your eye that enables your natural lens to move to focus on images at different distances. As part of the normal aging process, it has not had to work as it did when you were younger since you have seen at near through bifocal or reading glasses.

That is because your own lens has enlarged and hardened and become less flexible. Therefore, the muscle surrounding that lens is out of shape and must be exercised back into shape.

To achieve that end:

- Don't wear any reading glasses after the first two weeks
- Keep practicing until you can read comfortably without glasses (may be approx. 2 months but will probably improve over the first 12 months)
- You should wear sunglasses with UV 400 protection when in sunlight

And, remember:

- Your near vision may continue to improve for up to 12 months

Thank you for considering the Trulign Toric Accommodating IOL.